REMARKS/ARGUMENT

On page 9 of the current Office Action, the Examiner noted that the arguments being presented related to humans but the claims were not so limited. To eliminate this deficiency, claim 21 has been appropriately amended. Since the Examiner understood that the Applicant was intending to cover human use and the prior art rejections were based, at least in part, on the female being human, it is respectfully submitted that the amendment does not raise any new issue and this response should be considered on its merits.

The specification was objected to under 35 U.S.C. § 112, first paragraph, as failing provide an enabling disclosure. On page 3 of the Action, it is stated that the criteria that defines a SERM is not set forth. Applicant previously pointed out that both the SERM acronym and the full name "Selective Estrogen Receptor Modulator" were well known and well understood in the art and provided citations in support of that statement. On page 7 of the action, the Examiner has stated that the rejection is for undue experimentation rather than a failure to grasp what constitutes a SERM. Nevertheless, there is also a rejection of the claims under 35 U.S.C. § 112, second paragraph, on the grounds that the term SERM is indefinite. In light of the Examiner's statement in the Office Action and the evidence previously provided, it is respectfully submitted that any assertion that the SERM is indefinite is untenable and should be withdrawn.

With respect to the other member of the combination, the current Office Action does not address the claims as they exist. Indeed, both rejections under Section 112 are not directed to the claims as they exist but instead are predicated on covering a material which they do not, namely, an agent which not only exhibits progestogenic activity but is also effective to modulate the side effects.

The language "agent which exhibits progestogenic activity (which) is effective to modulate the side effects of the Selective Estrogen Receptor Modulator" is not present in the current claims. That language was replaced in an amendment dated February 28, 2001 and the claims which should be under consideration recite "an agent which exhibits progestogenic activity". The reference to modulating the side effects appears in a

"wherein" clause which explicitly states that the amount of the specified agent which exhibits progestogenic activity is that effective to modulate those side effects. The application discloses that the "agent which exhibits progestogenic activity" can be progesterone, a synthetic progestin analog or even an anti-progestin having antagonistic activity and then proceeds over approximately a page to give specific examples. There can be no question that what constitutes a progestogenic activity is clear and definite to those of ordinary skill in this art. The Office Action does not contest the fact that agents which exhibit progestogenic activity are known and since such agents are known, it is clear that the Section 112, second paragraph, indefiniteness rejection is untenable.

Both the SERM and the progestogenic agents are clear and definite. It is indicated on page 5 that any known SERM can be used. The specification indicates that the SERM should be combined with a progestogenic agent and the specification is presumptively correct. It is the Examiner's burden in the first instance to provide evidence or scientific reasoning to demonstrate that the specification is incorrect. Fiers v. Revel, 25 USPQ2d 1101 (Fed. Cir. 1993); In re Marzocchi, 169 USPQ 367, 369-70 (CCPA 1971). It is respectfully submitted that this burden cannot be met by criticizing the application for not providing enough working examples (which are not required in the first instance) or making conclusory statements about predictability without providing any basis in the literature or by affidavit. For these reasons, and also because it is believed that this rejection is based on a misinterpretation of the claims which actually exist, it is respectfully submitted that the enablement rejection should be withdrawn.

The rejection of claims 21-33 under 35 U.S.C. § 103 over Jones, Basu and Schane is respectfully traversed.

The Examiner had indicated that one of the reasons for this rejection is the claims were being read as being broader than the human female. This has been remedied above. It is also believed that the rejection is based, at least in part, on a misreading of the instant claims, as discussed above. In any event, there is no teaching or suggestion in any of the prior art of the use of a progestogenic agent in an amount which is effective to modulate the side effects of a SERM.

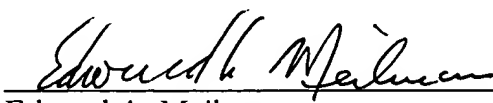
Schane teaches a particular progestogenic agent as an oral contraceptive. The other references were cited to show the use of SERMs to establish contraception but as previously pointed out, those references were published in the 1970s and reflect early beliefs about SERMs but do not reflect reality. SERMs, when used in premenopausal women, as claimed in this application, are fertility agents not contraceptive agents. The Examiner has not yet given any weight to the quoted statement from the Clark text because it was undated. In response, Applicant advises the Examiner that the date of Clark is 1994 (and that Yen is several years earlier). Clark establishes that at the time of the present invention, it was well known that SERMs were not contraceptive agents for premenopausal (or perimenopausal) women.

While the Office Action bases this rejection on the assumption that both the members of the combination have been used for the same purpose, it has been established that the SERMs are in fact fertility agents and not contraceptive agents and therefore the predicate for the asserted obviousness (used for the same purpose) is absent.

Beyond the foregoing, even assuming that both agents were known for the same purpose, the invention involves use of an amount of the progestogenic agent which modulates the side effects of the SERM. There is no teaching or suggestion that the progestogenic agent can do so in the cited art. Accordingly, it is respectfully submitted that the cited art is inadequate to negate the patentability of the claimed invention.

For all of the foregoing reasons, it is respectfully submitted that this application is now in condition to be allowed and the early issuance of a Notice of Allowance is respectfully requested.

Respectfully submitted,



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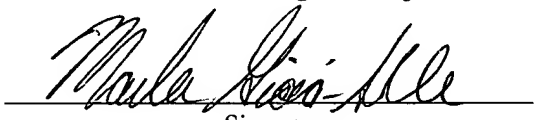

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APPENDIX A
"Clean" Version of Each Paragraph/Section/Claim
37 C.F.R. § 1.121(b)(ii) AND (c)(i)

CLAIMS (with indication of amended or new):

D 1

Amended 21. A method of achieving contraception in a premenopausal human female by administering to the female a contraception effective amount of a combination of a Selective Estrogen Receptor Modulator and an agent which exhibits progestogenic activity, wherein the amount of the agent which exhibits progestogenic activity is effective to modulate the side effects of the Selective Estrogen Receptor Modulator.

APPENDIX B
Version With Markings to Show Changes Made
37 C.F.R. § 1.121(b)(iii) AND (c)(ii)

CLAIMS:

21. A method of achieving contraception in a premenopausal **human** female by administering to the female a contraception effective amount of a combination of a Selective Estrogen Receptor Modulator and an agent which exhibits progestogenic activity, wherein the amount of the agent which exhibits progestogenic activity is effective to modulate the side effects of the Selective Estrogen Receptor Modulator.